EVALUATION OF THE HEALTH ASPECTS OF BENTONITE
AND CLAY (KAOLIN) AS FOOD INGREDIENTS

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Prepared for

Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
Washington, D.C.

Contract No. FDA 223-75-2004
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Life Sciences Research Office
Federation of American Societies
for Experimental Biology
9650 Rockville Pike
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NOTICE

This report is one of a series concerning the health aspects of using the Generally Recognized as Safe (GRAS) or prior sanctioned food substances as food ingredients, being made by the Federation of American Societies for Experimental Biology (FASEB) under contract no. 223-75-2004 with the Food and Drug Administration (FDA), U.S. Department of Health, Education, and Welfare. The Federation recognizes that the safety of GRAS substances is of national significance, and that its resources are particularly suited to marshalling the opinions of knowledgeable scientists to assist in these evaluations. The Life Sciences Research Office (LSRO), established by FASEB in 1962 to make scientific assessments in the biomedical sciences, is conducting these studies.

Qualified scientists were selected as consultants to review and evaluate the available information on each of the GRAS substances. These scientists, designated the Select Committee on GRAS Substances, were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. The Select Committee's evaluations are being made independently of FDA or any other group, governmental or nongovernmental. The Select Committee accepts responsibility for the content of each report. Members of the Select Committee who have contributed to this report are named in Section VII.

Tentative reports are made available to the public for review in the Office of the Hearing Clerk, Food and Drug Administration, after announcement in the Federal Register, and opportunity is provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the substances covered by the report. The data, information, and views presented at the hearing are considered by the Select Committee in reaching its final conclusions. Reports are approved by the Select Committee and the Director of LSRO, and subsequently reviewed and approved by the LSRO Advisory Committee (which consists of representatives of each constituent society of FASEB) under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the reports are approved and transmitted to FDA by the Executive Director of FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of all of the individual members of its constituent societies.

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## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>II. Background information</td>
<td>2</td>
</tr>
<tr>
<td>III. Consumer exposure data</td>
<td>4</td>
</tr>
<tr>
<td>IV. Biological studies</td>
<td>4</td>
</tr>
<tr>
<td>V. Opinion</td>
<td>9</td>
</tr>
<tr>
<td>VI. References cited</td>
<td>11</td>
</tr>
<tr>
<td>VII. Scientists contributing to this report.</td>
<td>15</td>
</tr>
</tbody>
</table>
I. INTRODUCTION

This report concerns the health aspects of using bentonite and clay (kaolin) as food ingredients. It has been based partly on the information contained in a scientific literature review (monograph) furnished by FDA (1), which summarizes the world's scientific literature from 1920 through 1974. * To assure completeness and currency as of the date of this report this information has been supplemented by searches of over 30 scientific and statistical reference sources and compendia that are generally available; use of new, relevant books and reviews and the literature citations contained in them; consideration of current literature citations obtained through computer retrieval systems of the National Library of Medicine; searches for relevant data in the files of FDA; and by the combined knowledge and experience of members of the Select Committee and the LSRO staff. In addition, announcement was made in the Federal Register of July 26, 1977 (42 FR 38017-38018) that opportunity would be provided for any interested person to appear before the Select Committee at a public hearing to make oral presentation of data, information, and views on the health aspects of using bentonite and clay (kaolin) as food ingredients. The Select Committee received one request for such a hearing on bentonite and clay (kaolin) but this request was withdrawn.

As indicated in the Food, Drug, and Cosmetic Act [21 USC 3(s)], GRAS substances are exempt from the premarketing clearance that is required for food additives. It is stated in the Act and in the Code of Federal Regulations (2) [21 CFR 170.3 and 170.30] that GRAS means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of substances on the basis of scientific data derived from published literature. These sections of the Code also indicate that expert judgment is to be based on the evaluation of results of credible toxicological testing or, for those substances used in food prior to January 1, 1958, on a reasoned judgment founded in experience with common food use, and is to take into account reasonably anticipated patterns of consumption, cumulative effects in the diet, and safety factors appropriate for the utilization of animal experimentation data. FDA (2) recognizes further that it is impossible to provide assurance that any substance is absolutely safe for human consumption.

*The document (PB 234 893/6) is available from the National Technical Information Service, U.S. Department of Commerce, P.O. Box 1553, Springfield, Virginia 22161.
The Select Committee on GRAS Substances of LSRO is making its evaluations of these substances in full recognition of the foregoing provisions. In reaching its conclusions on safety the Committee, in accordance with FDA's guidelines, is relying primarily on the absence of substantive evidence of, or reasonable grounds to suspect, a significant risk to the public health. While the Committee realizes that a conclusion based on such reasoned judgment is expected even in instances where the available information is qualitatively or quantitatively limited, it recognizes that there can be instances where, in the judgment of the Committee, there are insufficient data upon which to base a conclusion. The Committee is aware that its conclusions will need to be reviewed as new or better information becomes available.

In this context, the LSRO Select Committee on GRAS Substances has reviewed the available information on bentonite and clay (kaolin) and submits its interpretation and assessment in this report, which is intended for the use of FDA in determining the future status of these substances under the Federal Food, Drug, and Cosmetic Act.

II. BACKGROUND INFORMATION

Bentonite and clay (kaolin) are members of a large class of naturally occurring minerals and consist of hydrated aluminum silicates. They are secondary mineral formations containing varying quantities of iron, alkalies, and alkaline earths in the commercial products (3). The structures of these substances have been determined by x-ray diffraction analysis (4). Bentonite is composed largely of smectite, the unit cell structure consisting of one layer of \( \text{Al}_2\text{O}_3 \) sandwiched between two layers of \( \text{SiO}_2 \). The unit cell structure of clay (kaolin) has two layers. One layer is composed of \( \text{Al}_2\text{O}_3 \) molecules and the other of \( \text{SiO}_2 \) molecules. The two layers are stacked one over the other, with the flat sides together (4, 5). Far infra-red spectrography has been used to distinguish between some varieties of these clay minerals (6).

Depending on the cations present, natural deposits of bentonite range in color from white to gray, yellow, green, or blue. When dry, commercial bentonite is usually a very fine, pale buff or cream-colored powder; it is odorless with a slight earthy taste. A relatively small but variable proportion of the cations of bentonite can undergo exchange with certain other ions. A bentonite can be modified by replacing the exchangeable cations and these cations determine certain of its physical properties,
especially its hydration; the predominance of sodium in the exchangeable cation fraction imparts capability for a high degree of hydration, a property that is lowered by a predominance of calcium. Bentonite is insoluble, but when mixed with 8 to 14 parts of water it swells to produce a slippery paste resembling petroleum jelly. In aqueous suspensions the particles are negatively charged, thus attracting and binding positively charged particles (3).

At least three different minerals (kaolinite, dickite, and nacrite) are classified as kaolin. Kaolinite, or china clay is whiter, less contaminated with extraneous minerals, and less plastic in water as a result of its microcrystalline structure compared with the amorphous form of other clays. While bentonite and clay (kaolin) are similar chemically, bentonite's finer particles provide greater total surface area and hence, more pronounced adsorptive capacity (3).

No food grade specifications for bentonite have come to the attention of the Select Committee. The U.S. Pharmacopeia (7) describes medicinal grade bentonite, but provides no limiting specifications. The Food Chemicals Codex (8) specifies limits of impurities for clay (kaolin) as:

- Loss on ignition > 15 percent
- Acid-soluble substances > 2 percent
- Arsenic (as As) > 3 ppm (0.0003 percent)
- Heavy metals (as Pb) > 40 ppm (0.004 percent)
- Lead > 10 ppm (0.001 percent)

The Code of Federal Regulations (2) lists bentonite as GRAS under 21 CFR 182.1155 as a multiple purpose GRAS food substance and in 21 CFR 175.105, 175.300, and 176.170 as a substance that may be safely used as a component of coatings and adhesives, and as a component of paper and paperboard that may come in contact with aqueous and fatty foods. Bentonite (Wyoming clay) is also authorized under 27 CFR 240.1051 (9) as a substance considered safe for the clarification of wine. The use of bentonite, presumably also for the purposes of clarification, has received approval in making certain corn products for food use (10). However, no specific instance has come to the attention of the Select Committee in which the current use of bentonite in the processing of foods for human consumption results in the retention of this substance in the final product. It is to be noted that sodium bentonite has been used as an effective bonding agent for pelleted feeds (11-13) for a number of years; the level should not exceed 2.5 percent to avoid loss of vitamin A activity. Sodium bentonite (sodium aluminosilicate or sodium silicoaluminate) is considered in another report of the Select Committee (14) and is not evaluated in the present report.
The Code of Federal Regulations (2) lists clay (kaolin) as GRAS under Section 21 CFR 182.90 as a substance migrating to food from paper and paperboard products used in food packaging. A use has been reported for a modified clay (kaolin) as an anticaking agent or conditioner in the processing of soybean meal as a feed (15), but no specific instances of such a use in foods intended for human consumption have come to the attention of the Select Committee.

III. CONSUMER EXPOSURE DATA

A subcommittee of the National Research Council (NRC) surveyed manufacturers concerning the addition of GRAS substances to foods in 1970 and estimated the possible average daily intake of these substances by various age groups (16). Bentonite and clay (kaolin) were included in the survey, but there was no report from the manufacturers surveyed that these substances were added as ingredients of any foods. The Select Committee has found no data concerning the amount of clay (kaolin) that might be abraded from food packaging materials when it is used as an ingredient of coatings or adhesives, but believes the amounts could only be small.

Instances of deliberate clay eating (pica) by humans are documented (17). The clays consumed have generally been the unrefined minerals obtained as they are found naturally. The amounts consumed per day by clay eaters who have been studied have ranged from about 6 to 130 g (0.1 to 2.2 g per kg) (18).

IV. BIOLOGICAL STUDIES

Absorption, excretion, and biochemical aspects

While no studies performed specifically to examine the absorption of either bentonite or clay (kaolin) have come to the attention of the Select Committee, the following reports are relevant.

Riecken et al. (19) fed rats as much as four parts kaolin to one part of diet for as long as 12 weeks and concluded from histological studies that very little if any kaolin was absorbed. Boyd et al. (20) compared the acute oral toxicity of powdered iron with that of kaolin in rats and concluded that the amount of kaolin absorbed and the reaction to its absorption bore little or no relation to the dose of kaolin administered intragastrically. They believed kaolin to be inert except for danger of bowel obstruction.
resulting in perforation. The clinical signs such as listlessness, anorexia, oliguria, hypothermia, and dyspnea, were apparently due to pathological reaction from over-distension of the alimentary canal by an inert solid substance. This reaction to distension was as marked following a kaolin dose of 100 g per kg as it was following 210 g per kg. The number of fatalities and the incidence and advance of bowel obstruction along the small intestine were dose-related.

Consideration has been given to the effect of different kinds of clay on the absorption of iron in normal and iron-deficient human subjects. Using $^{65}\text{FeSO}_4$ and $^{59}\text{Fe}$ hemoglobin, Minnich et al. (21) found that clays differ in their effects but exchange with iron occurred in all except in a sample of clay obtained from New Mexico. The New Mexico clay was described as "stony-hard", as compared with the other clays studied which were described as fine and soft with a greater surface area for cation exchange. The subjects ingested 5 g of clay (about 80 mg per kg). In general, the average radioactive iron absorbed when administered with clay was about 8 percent and without it, about 13 percent.

Mixtures of kaolin and pectin have been given orally as water absorbents in the symptomatic treatment of diarrhea; controlled clinical studies that demonstrate the efficacy of this mixture are lacking, but there is no evidence of acute adverse effects. Kaolin in this form of medication is contraindicated in patients with obstruction of the bowel (22). The usual dose of kaolin is 15 to 60 g (3).

**Acute toxicity**

No information has come to the attention of the Select Committee on the acute toxicity of bentonite. However, some data on clay (kaolin), based on experiments performed by Boyd, et al. (20) on 120 to 140 young male albino rats weighing 90 to 100 g, were obtained in a study of death from bowel obstruction. Range of doses was determined by a review of the literature which indicated that a dose of 50 g per kg would have no effect. A thin suspension of kaolin in distilled water was administered intragastrically in doses of 100, 110, 120, 140, 145, 150, 155, 160, 175, and 210 g per kg, while 14 control animals were given 150 ml per kg distilled water. The dose which killed 50 percent of the rats by bowel obstruction, the ED$_{50}$, was 149 g per kg, the ED$_1$, was 110 g per kg, and the ED$_{100}$, was 188 g per kg.

**Short-term studies**

Bentonite, kaolin and other clays have been used in animal feeds chiefly as pellet binders for many years (23). Suitability of these substances for such use has been supported by several studies on chicks and rats.
When either sodium bentonite or calcium bentonite was added at a level of 2 to 3 percent (about 4.5 g per kg initial body weight per day) or higher, in a purified diet containing adequate amounts of vitamin A in unstabilized form, chicks developed signs of vitamin A deficiency (13). All signs of deficiency were prevented by the use of stabilized vitamin A, by higher levels of unstabilized vitamin A or carotene, or by injection of vitamin A. Chemical analysis of the purified diet at intervals after preparation showed that there was appreciable disappearance of vitamin A (37 percent in 2 hours, 58 percent in 5 days) in the presence of sodium bentonite. When the bentonite was 90 mesh or coarser no evidence of vitamin A deficiency was noted unless the level of bentonite was increased to approximately 20 percent. This level depressed growth and feed efficiency. No evidence was obtained to indicate that bentonite was not acceptable at the level commonly used in pelleted feeds (2.5 percent). Chicks fed 5 percent kaolin in the diet showed no signs of vitamin A deficiency or growth depression. In experiments on broilers fed a basal ration including yellow corn, soybean meal, fish meal, and vitamin and mineral supplement, the inclusion of two different sources of kaolin or one source of calcium bentonite at levels of 1 percent (about 1.5 g per kg initial body weight per day) or 2 percent in the ration improved the growth rate, but at the 3 percent level there was no improvement in growth rate (23). At levels of 5 percent and 10 percent both kaolins and bentonite tended to depress the growth rate, but with no apparent effect on caloric efficiency. The slight adverse effect on growth apparently was attributed to the appreciable dilution of the total diet with these non-nutrient substances.

Sibbald et al. (24) fed a chick starter diet plus 0, 6, 12, 18, 24, 30, 36, and 42 percent (about 7 to 50 g per kg final body weight per day) kaolin to young chicks. A three day adjustment period was followed by a seven day test period during which weight gain and feed consumption were reported. The weight gains were equivalent to controls at the 6 and 12 percent levels, but decreased sharply at the 18 percent level and above. Feed consumption was high for all the birds consuming kaolin. There was no evidence of adverse effects other than a depressed weight gain for the animals on kaolin at the higher levels.

Commercial feed admixed with 2 percent or 3 percent bentonite was fed for one year to beef and dairy cattle (25, 26). Overall health of the animals remained unchanged. The biochemical indices measured were as good or better in the test groups than in the controls, and the average annual weight gain or milk production was greater in the bentonite-fed animals. Similarly, daily doses of 15 g in sheep had no adverse effects on their health, appetite or rumination (27).
Very high levels of kaolin in the diet depressed growth rate in rats (28). Groups of 20 inbred, hooded rats weighing 90 g were fed a standard laboratory ration containing 0, 66, or 80 percent by weight of powdered kaolin for 9 to 12 months. After 39 weeks, the animals receiving the 66 percent kaolin diet averaged a body weight gain of 164 g, those receiving the 80 percent kaolin diet gained an average of 139 g, and the controls 182 g. Animals at the 66 percent level consumed about three times as much feed as the controls; animals at the 80 percent level consumed nearly five times as much feed as the controls. There was no dilatation or hypertrophy of the small intestine, but the jejunum showed a marked increase in absorptive capacity of glucose and water as measured by an everted sac technique. There was dilatation of the cecum and the large intestine was significantly heavier than that of the control animals; this was attributed to an increased thickness of the muscle coat. No pathological changes were observed.

Kennedy (29) studying 150 to 450 g rats with electrolytically induced hypothalamic lesions, fed diets containing 50 percent kaolin (average of about 30 g per kg per day) for up to 110 days. The rats had voracious appetites induced by the surgical procedure and became obese. Control (unoperated) rats maintained normal growth rate on the same diet.

Riecken et al. (19) fed adult rats a standard laboratory ration containing powdered kaolin at levels of 0, 66, or 80 percent (about 33 to 40 g per kg body weight). Animals examined after 2, 5, 4, and 12 weeks exhibited no apparent hypertrophy of the small intestine. There was an increase in the activity of intestinal leucine amino-peptidase and several dehydrogenases, but no pathological changes were noted.

Sodium bentonite, fed for 1 to 4 weeks (to animals previously on a vitamin A deficient diet) at levels of 0.5 to 3.5 percent (about 0.4 to 2.8 g per kg body weight) in purified diets, caused a lowering of the level of vitamin A in the livers of rats presumably due in part to the physical adsorption of vitamin A by sodium bentonite in the small intestine (11). This occurred whether or not a stabilized form of vitamin A was used.

Mice fed bentonite at levels of 0, 10, 25, or 50 percent in the diet for 60 days, showed slight growth impairment at the 10 and 25 percent levels (about 15 g and 40 g per kg body weight per day) and extreme growth impairment at the 50 percent level. At the highest bentonite level, but not at the two lower levels, animals developed signs of choline deficiency and fatty livers (30). Retarded growth rate and fatty livers were also found in mice fed diets containing 30 percent bentonite (31).

Many instances of human craving for clay have been recorded. Edwards et al. (18) for example, studied 38 pregnant and 4 non-pregnant
women who practiced clay-eating in Alabama. The quantity of clay consumed per day ranged from about 6 to 130 g (about 0.1 to 2.2 g per kg body weight). Many of the women obtained the clay from a river or stream banks near their homes. In some cases, the clay was baked in the oven prior to consumption. In their experience and in their review of the literature on human clay eating, Edwards et al. found no indications of any unfavorable consequences of the practice, except some impairment of iron utilization when large amounts of clay were ingested.

**Long-term studies**

Reports of long-term animal feeding studies on bentonite or clay (kaolin) have not come to the attention of the Select Committee.

**Special studies**

Wilson (32) noted that hepatomas developed in 11 of 12 mice fed for about eight months on a semi-purified low-protein diet containing 50 percent bentonite (about 50 g per kg). He concluded that this might have been caused, at least partially, by choline deficiency induced by the removal of choline through a cationic exchange on the bentonite, but did not exclude the possibility that there may have been other factors (33). These results were consistent with the earlier studies of Engel et al. (34), who reported hepatomas in rats fed diets low in choline and other sources of available methyl groups.

Cohn et al. (35) studied one man who had used various medications (including colloidal kaolin) for several years apparently for treatment of duodenal ulcer. Microscopic examination of tissue from the prepyloric region revealed a few small granulomatous lesions. This led to a limited study of four rabbits fed a daily diet containing powdered colloidal kaolin (dose not stated). The rabbits were prepared, before feeding, by lightly curetting a small area of the stomach mucosa. After periods of time up to four months, the tissues were examined microscopically and compared with tissues obtained from other rabbits prepared by the injection of the colloidal kaolin into the gastric mucosa. The tissues of both groups were essentially alike. In all the tissues the characteristic giant cells had multiple nuclei, and they "occurred singly or in groups and were encapsulated by a fine loose connective tissue surrounded by lymphocytes, plasma cells and eosinophilic neutrophils." Colorless refractile crystals, characteristic of silica, were present in many of the giant cells. These crystals resembled those observed in the kaolin preparation used by the patient and administered to the rabbits.

- 8 -
In a study of 16 macaques, Reed et al. (36) found subcutaneous cervical or mediastinal granulomas in tissues damaged by faulty esophageal intubations of kaolin preparations. With one exception, the lesions were relatively benign. Elongated and irregularly outlined, highly birefringent crystals observed in all the affected tissues were identified as kaolinite.

No experimental studies concerning mutagenicity or teratogenicity of bentonite or clay (kaolin) have come to the attention of the Select Committee.

Other compounds of aluminum (37) and silicon (14) have been or will be evaluated in other reports of the Select Committee.

V. OPINION

Bentonite and clay (kaolin) are readily hydratable aluminum silicates. Bentonite is used to assist in the clarification of juices, beverages, and other food products, as a binding agent for the preparation of pelleted animal feeds, and as an ingredient of coatings and adhesives for food packaging materials. The Select Committee is not aware of any instance in current practice where use of bentonite in the processing or packaging of foods for human consumption results in the retention of more than minute amounts in the final product and assumes the current practice will continue. Nevertheless, food grade standards for bentonite should be established, particularly with respect to soluble constituents and heavy metal cations that may be present in commercial products.

Clay (kaolin) is GRAS only as an ingredient of paper and paperboard products used in food packaging. There are no data available concerning the amounts of clay (kaolin) that might migrate to foods from this source but the Select Committee believes the amounts can only be very small.

Apparently, very little, if any, bentonite is absorbed after oral administration and as much as 3 percent in the diet has no observable adverse effects on experimental animals. Diets containing 10 to 25 percent can cause growth retardation both because of dilution of the diet and the tendency of some bentonites to adsorb vitamin A in mixed diets and otherwise interfere with the absorption of this vitamin in the intestinal tract.

Very little, if any, kaolin is absorbed after oral administration. Bowel obstruction occurs at very high doses, about 100 g per kg body weight in rats being fatal to 1 percent, about 150 g per kg being fatal to 50 percent.
No adverse effects have been observed at dietary levels as high as 12 percent in experimental animals. The human therapeutic dose for diarrhea is about 250 to 1,000 mg per kg.

It is noted that clay (kaolin) administered under conditions that damage mucosal tissues, tends to produce granulomatous lesions. However, the generally high tolerance for kaolin under normal conditions makes it improbable that such effects could result as it is currently used.

Based upon consideration of the data presented in this report and assuming the establishment of appropriate food grade standards for bentonite, the Select Committee concludes that:

There is no evidence in the available information on bentonite that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when it is used in the manner now practiced or that might reasonably be expected in the future.

There is no evidence in the available information on clay (kaolin) that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used as an ingredient of food packaging materials in the manner now practiced or that might reasonably be expected in the future.
VI. REFERENCES CITED


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